Application No. 10/510,028

Attorney Docket No. 060960-5053US

Amendment dated

Response to Office action dated May 21, 2010

Remarks/Arguments:

This Amendment and Response is responsive to the final Office action dated May 21, 2010.

Status of the Claims:

Claims 1-4, 10, 17, 21, 26, 31-56 are currently pending. Claims 1-4, 10, 17, 21, 26, 31-36, 38-51 are currently under examination and form the basis of the present Office action. By the present Amendment claim 10 has been canceled and claims 1, 21, 40, 43 and 49 have been amended. Support for the amendment can be found at least in the originally filed claims and throughout the specification. No new matter has been added.

All amendments and cancellations presented herein are made to expedite prosecution of the application without admission as to the propriety of the objections and rejections set forth in the present Office Action and without acquiescence to the Examiner's characterization of the claims or prior art. Applicants respectfully reserve the right to include claims of the same or different scope as previously written in one or more continuing applications.

Claim Rejections:

Claim 40 is rejected under 35 U.S.C. § 112, second paragraph, as allegedly having A. insufficient antecedent basis for the recitation "wherein a concentration of the ready-touse, hydrated hydrogel or a ready-to-use, hydrated substance which can be swollen into a hydrogel."

Applicants submit that amended claim 40 has sufficient antecedent basis in independent claim 1 and request that the rejection of claim 40 under 35 U.S.C. § 112, second paragraph, has be withdrawn.

В. Claims 1, 21, 31-36, and 38-39 stand rejected on the basis of nonstatutory obviousness-type double patenting, as allegedly patentably indistinct from claims 1, 3, 19-21, 27-31,33-34 and 36 of US 6,733,582 (hereinafter "Bohner-582").

Without admission as to the propriety of the non-statutory obviousness-type double patenting and without acquiescence to the Examiner's characterization of the claims or BohnerApplication No. 10/510,028 Attorney Docket No. 060960-5053US Amendment dated __ Response to Office action dated May 21, 2010

582, Applicants note that claim 1 has been amended. Applicants respectfully request that the Office reconsider and withdraw the nonstatutory double patenting rejection.

C. Claims 1-4, 17, -494 and Lee-456.

Claims 1-4, 17, 21, 31-36, and 38-49 stand rejected under 35 U.S.C. § 103(a), as being allegedly obvious either over Bohner-582 in view of Rhee-418 and further in view of Li-104, Coombes-494 and Lee-456; or as allegedly obvious over Bohner-824 Bohner-582 in view of Rhee-418 and further in view of Starling-715, Coombes-494 and Lee-456.

Amended independent claim 1 reads:

"A kneadable and moldable bone-replacement material which consists of a mixture of:

- A) calcium-containing ceramic particles wherein the ceramic particles comprise a calcium to phosphate ratio having a molar Ca/P relationship between 1.0 and 2.0, wherein the calcium phosphate is selected from the following group: dicalcium phosphate dihydrate (CaHPO₄•2H₂O); dicalcium-phosphate (CaHPO₄); alpha-tricalcium-phosphate (α-Ca₃(PO₄)₂); betatricalcium-phosphate (β-Ca₃(PO₄)₂); calcium-deficient hydroxylapatite (Ca₉(PO₄)₅(HPO₄)OH); hydro-xylapatite $(Ca_{10}(PO_4)_6OH)_2)$; carbonated apatite $(Ca_{10}(PO_4)_3(CO_3)_3(OH)_2)$; flourapatite (Ca₁₀(PO₄)₆F₂); chlorapatite (Ca₁₀(PO₄)₆Cl₂); whitlockite; tetracalcium phosphate (Ca₄(PO₄)₂O); oxyapatite $(CA_{10}(PO_4)_6O)$; beta calcium pyrophosphate (β -Ca₂(P₂O₇); alpha calcium pyrophosphate; gamma calcium pyrophosphate; and octocalcium-phosphate (Ca₈H₂(PO₄)₆•5H₂O); wherein a bulk density of the ceramic particles is between 0.6 g/cm³ and 1.0 g/cm³; and wherein an average diameter of the ceramic particles is between 100 and 500 um; and
- B) a hydrogel or a substance that can be swelled into a hydrogel, and wherein:
 - C) the ceramic particles are of fully synthetic origin;
- D) the individual ceramic particles have <u>a porosity of 60</u> percent to 90 percent; and
- E) the majority of the ceramic particles have a non-spheric shape."

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Bohner-582 does not disclose, teach or suggest all of the limitations of independent claim 1. In particular Bohner-582 fails to disclose, teach or suggest the above-underlined language as claimed.

Rhee-418, Li-104, Starling-715, Coombes-494 and Lee-456 also fail to disclose, teach or suggest the underlined language as claimed.

The Office contends at page 9 of the Office action that "715 teaches that microspheres of CaP (calcium phosphate) for implantation have a porosity of about 60% with a pore size of 350-500 microns (abstract, col. 9, lines 2-5)." Applicants respectfully traverse this characterization for at least the following reason.

Applicants respectfully submit that Starling-715 does not disclose, teach, or suggest the underlined language as claimed. In particular, Starling-715 discloses "interstitial open porosity of about 60% with a pore size range of about 350 micrometers to about 500 micrometers" (emphasis added) (Starling-715, col. 9, lines 2-5). Starling-715 does not teach "individual ceramic particles have a porosity of 60 percent to 90 percent" as claimed. Therefore, Starling fails to remedy the deficiency of Bohner-582. Accordingly, Applicants submit that independent claim 1 is allowable over Bohner-582 alone or in combination with Rhee-418, Li-104, Starling-715, Coombes-494 and Lee-456. Applicants further submit dependent claims 2-4, 17, 21, 31-36, and 38-49 are also allowable over Bohner-582 alone or in combination with Rhee-418, Li-104, Starling-715, Coombes-494 and Lee-456.

For at least the foregoing reasons, Applicants request reconsideration and withdrawal of the rejection.

D. Claims 1-4, 10, 17, 21, 31-36, and 38-51 are patentable over both (a) US 2001/0053938 (hereinafter "Dorigatti-938") Rhee-418, Li-104, Coombes-494 and Lee-456; and (b) Dorigatti-938, Rhee-418, Starling-715, Coombes-494 and Lee-456.

Claims 1-4, 10, 17, 21, 31-36, and 38-51 stand rejected under 35 U.S.C. § 103(a), as allegedly being either obvious over Dorigatti-938 in view of Rhee-418 and further in view of Li-104, Coombes-494 and Lee-456; or as being obvious over Dorigatti-938 in view of Rhee-418 and further in view of Starling-715, Coombes-494 and Lee-456.

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Applicants respectfully submit that Dorigatti-938 does not disclose, teach or suggest the underlined language as claimed in independent claim 1. Since none of Rhee-418, Li-104, Starling-715, Coombes-494 and Lee-456 discloses, teaches or suggests the underlined language as claimed, Dorigatti-938 in combination with these references also does not disclose, teach or suggest the underlined language as claimed. Therefore, Applicants submit that independent claim 1 is allowable over Dorigatti-938 alone or in combination with Rhee-418, Li-104, Starling-715, Coombes-494 and Lee-456. Applicants further submit that dependent claims 2-4, 10, 17, 21, 31-36, 38-51 are also allowable over Dorigatti-938, Rhee-418, Li-104, Starling-715 and Lee-45 for at least depending directly or indirectly from allowable claim 1. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a).

Conclusion:

Applicants respectfully submit that each rejection of the claims of the present application has been overcome and respectfully submit that all the claims under consideration are in condition for allowance. Reconsideration and allowance of these claims are respectfully requested. Should the Examiner wish to discuss any aspect of this application, Applicants' representatives suggest a telephonic interview to expedite allowance of the present application.

The Director is hereby authorized to charge any necessary fees, including RCE fees and extension fees under 37 C.F.R. § 1.17(a), or credit any overpayments in connection with this submission to Deposit Account No. **50-0310** (Billing No. 060960-5053US).

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Respectfully submitted,

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Date: October 12, 2010 By: /Robert P. Udal/

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